JUL 2 8 2014
K140313

510(k) Summary

CoAg StopsBleeding™ Topical Hemostat Powder and Foam

Date Prepared: February 7, 2014

Submitter: CoAg Medical LLC
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Contact: Mr. Bernard Horwath
Regulatory Affairs Consultant
4486 Timberline Ct
Vadnais Heights, MN 55127
Telephone: 651- 231-1761

Proprietary Name: StopsBleeding™ Topical Hemostat Powder and Foam

Common/Usual Name: Topical hemostatic particles

Classification Name: Dressing, Pre-Amendment Unclassified
Product Code – FRO General and Plastic Surgery

Description:
The CoAg Medical StopsBleeding™ Topical Hemostat Powder and Foam are sterile, topical wound dressings comprised of plant based polysaccharides that accelerate the coagulation process to form a stable clot. The hemostatic particles contained in both the powder form and the foam form accomplish this by quickening the natural drying process at the wound site and by concentrating the vital nutrients (proteins and platelets etc.) that the body uses to naturally form a clot. When more of these nutrients are present at a wound site, the body is able to accelerate the cessation of bleeding and allow the healing process to more quickly and naturally occur on its own.

Indications for Use:
The CoAg Medical, LLC StopsBleeding™ Topical Hemostat Powder and Foam are intended for use as a topical dressing for the management of bleeding wounds and are available for prescription use and over-the-counter use.

Prescription: StopsBleeding™ Rx Topical Hemostat Powder and Foam are indicated for use as a topical dressing for the temporary treatment of moderate to severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), cuts and lacerations and are also indicated for control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites. StopsBleeding™ Rx is intended for use under the care of a health care professional.

OTC: StopsBleeding™ OTC Topical Hemostat Powder and Foam are indicated for use as a topical dressing on minor bleeding wounds such as cuts, lacerations and abrasions and for minor nose bleeds.

Substantial Equivalence:
The CoAg Medical StopsBleeding™ Topical Hemostat Powder and Foam are substantially equivalent to the following predicate devices:

Manufacturer	Brand Name	510(k) Number
Hemostasis, LLC	TraumArrest®/BleedArrest®	K070211
Medafor	Bleed-X™/Traumadex™	K013225

StopsBleeding™ Topical Hemostat Powder and Foam are technically identical hemostats as the predicates and have the same intended use. The Hemostasis, LLC hemostat is considered the primary predicate for indications for use, technical composition and performance, while the Medafor hemostat predicate has substantially equivalent packaging.

Technological Characteristics:
Technically, the StopsBleeding™ Topical Hemostat Powder and Foam have the same plant based polysaccharide material composition as the predicates. The use of this same potato starch polysaccharide in the CoAg and Hemostasis hemostats results in the same mechanism of action, namely dehydration of blood cells and hemoconcentration of platelets and serum proteins leading to clotting.

Biocompatibility:
The CoAg Medical StopsBleeding™ Topical Hemostat Powder and Foam and the predicate hemostats are categorized as a surface device for breached or compromised skin surfaces with prolonged exposure of 24 hours to 30 days in accordance with ISO 10993-1 *Biological Evaluation of Medical Devices*. These plant based polysaccharides hemostats have demonstrated compliance to cytotoxicity, sensitization and irritation biocompatibility testing and have a long history of safe and effective use.

Sterilization:
The CoAg Medical StopsBleeding™ Topical Hemostat Powder and Foam are sterilized using a gamma radiation method to assure a sterilization assurance level (SAL) of 10^{-6}. The CoAg devices are packaged in the same manner as the predicate devices to assure sterility over their labeled shelf life.

Bench Testing:
Design verification testing was performed on StopsBleeding™ Topical Hemostat Powder and Foam to demonstrate physical and functional requirements were met.

Performance Testing:
Comparative water holding capability bench testing and bleeding cessation testing in a porcine animal model demonstrated that the StopsBleeding™ Topical Hemostat Powder and Foam performed substantially equivalent to the primary predicate devices.

Conclusion:
Through the data and information presented, CoAg Medical, LLC considers the StopsBleeding™ Topical Hemostat Powder and Foam substantially equivalent to the predicate devices already on the market (cleared by the 510(k) process) in terms of indications for use, scientific technology, material composition, design, functional performance, and sterility/packaging and present no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 28, 2014

CoAg Medical LLC
% Mr. Bernard Horwath
Regulatory Affairs Consultant
4486 Timberline Court
Vadnais Heights, Minnesota 55127

Re: K140313
Trade/Device Name: CoAg StopsBleeding™ Topical Hemostat Powder and Foam
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 27, 2014
Received: July 1, 2014

Dear Mr. Horwath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140313

Device Name
CoAg StopsBleeding™ Topical Hemostat Powder and Foam

Indications for Use *(Describe)*

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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